IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE DEPAKOTE:	)	
	)	
H.B., a minor, by STACY BARTOLINI individually and as parent and next friend of H.B.,	)	
	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**Case No. 15-CV-702-NJR-SCW**
	)	
ABBOTT LABORATORIES, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER

ROSENSTENGEL, District Judge:

Pending before the Court is a motion for summary judgment filed by Defendant Abbott Laboratories, Inc. ("Abbott") directed at the claims of Plaintiff H.B. and his parent Stacy Bartolini. (Doc. 348). For the reasons set forth below, Abbott's motion for summary judgment is denied.

Introduction & Procedural Background

These Depakote cases involve a mass tort action in which numerous plaintiffs allege they sustained personal injuries from the use of Abbott's prescription drug Depakote.[1] On April 27, 2015, the Court selected the following three bellwether cases for trial: H.B. and parent Stacy Bartolini (12-CV-53), T.C. and parent Kayla McGuinness

[1]"Depakote" or "Depakene" refers to Abbott's pharmaceutical drug with the basic ingredient valproic acid. Depakote is also sometimes referred to by the chemical names "valproic acid," "valproate," or "divalproex sodium."

(12-CV-694), and E.R.G. and parent Christina Raquel (12-CV-55). (*See* Case No. 15-cv-702, Doc. 1). For case management and docket control purposes, the Court opened a new case number, 15-cv-702-NJR-SCW, for these three cases only (12-CV-53, 12-CV-694, 12-CV-55).

In September 2017, Abbott filed a motion for summary judgment in the Bartolini case. (Doc. 348). At issue in this litigation is the adequacy of the 2004 Depakote warning label. Generally, Plaintiffs contend that the 2004 label failed to disclose important facts relating to the risk of spina bifida and other birth defects. Abbott contends that Maryland law governs in this case and that under Maryland law the warning label is reasonable as a matter of law.

Factual Background

Plaintiff H.B. was born with spina bifida, and other alleged physical and cognitive injuries, in December 2004. (Doc. 372, p. 2). Plaintiffs attribute H.B.'s injuries to the use of Abbott's drug Depakote by his mother, Stacy Bartolini ("Ms. Bartolini"), while pregnant with H.B. In the First Amended Complaint, Plaintiffs bring claims against Abbott under theories of strict products liability (Count I) and negligence (Count II). (Case No. 12-cv-53, Doc. 2-8, pp. 49-51).

Dr. Stewart Bramson prescribed Depakote for Ms. Bartolini to treat her bipolar disorder. (Doc. 372, p. 2). Ms. Bartolini was a resident of Maryland when she was prescribed Depakote. The prescription of Depakote and Ms. Bartolini's consumption of Depakote occurred in Maryland. (Doc. 348, p. 3). On or around March 24, 2004, H.B. was conceived within the state of Maryland. Ms. Bartolini continued to use Depakote

until that use was discontinued nine to fourteen weeks into the gestational period. (Doc. 372-3, p. 5); (Doc. 348, p. 3). Ms. Bartolini moved from Maryland to North Carolina in August 2004 (Doc. 348-3, p. 3), and she gave birth to H.B. in North Carolina, which is the state where H.B. was treated for his injuries. (Doc. 372-3, pp. 5-9).

Abbott is incorporated in Delaware and has its principal place of business in Illinois. (Doc. 372, p. 3). Since 1984, Abbott's labeling for Depakote has contained information about the risk of spina bifida, and it has contained a Black Box Warning since 1996. (Doc. 348, p. 1). The 2004 FDA-approved Depakote label informed physicians that the incidence of spina bifida was 1-2%. (Doc. 348, p. 2). But the 2004 label at issue also "failed to disclose a major malformation rate for all birth defects caused by or associated with *in utero* Depakote exposure, indicat[ed] a similar association between Depakote and other AEDs," and failed to advise physicians to only prescribe Depakote as a drug of last resort for women of childbearing potential. (Doc. 372, pp. 3-4).

Legal Standard

Summary judgment is only appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Spurling v. C & M Fine Pack, Inc.*, 739 F.3d 1055, 1060 (7th Cir. 2014) (quoting Fed. R. Civ. P. 56(a)). Once the moving party has set forth the basis for summary judgment, the burden then shifts to the nonmoving party who must go beyond mere allegations and offer specific facts showing that there is a genuine issue of fact for trial. Fed. R. Civ. P. 56(e); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986).

The nonmoving party must offer more than "[c]onclusory allegations, unsupported by specific facts," to establish a genuine issue of material fact. *Payne v. Pauley*, 337 F.3d 767, 773 (7th Cir. 2003) (citing *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1990)). In determining whether a genuine issue of fact exists, the Court must view the evidence and draw all reasonable inferences in favor of the party opposing the motion. *Bennington v. Caterpillar Inc.*, 275 F.3d 654, 658 (7th Cir. 2001); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A "court may not assess the credibility of witnesses, choose between competing inferences or balance the relative weight of conflicting evidence . . . ." *Reid v. Neighborhood Assistance Corp. of Am.*, 749 F.3d 581, 586 (7th Cir. 2014) (quoting *Abdullahi v. City of Madison*, 423 F.3d 763, 769 (7th Cir. 2005)).

Analysis

I. What Law Governs the Reasonableness of the Warning Label?

Federal courts sitting in diversity "use the whole law of the forum state, including that state's choice-of-law rules." *Malone v. Corr. Corp. of Am.*, 553 F.3d 540, 542 (7th Cir. 2009). Illinois applies its choice-of-law rules on an "issue by issue basis." *Smith v. I-Flow*, 753 F. Supp. 2d 744, 747 (N.D. Ill. 2010). The Court only needs to determine which law should apply in a matter when it will impact the outcome. *Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 898 (Ill. 2007). Abbott asserts Maryland law governs the reasonableness standard for warning labels. (Doc. 348, p. 3). Abbott states H.B. "was conceived and developed spina bifida in Maryland, which is the state in which Stacy Bartolini was prescribed Depakote by a Maryland doctor and took Depakote." (Doc. 348, p. 3). There is no dispute in this case that spina bifida occurs within

approximately the first twenty-eight days of gestation. There is also no dispute that from the first prescription of Depakote to H.B.'s mother, through the first twenty-eight days of gestation, Ms. Bartolini resided in Maryland. Nevertheless, Plaintiffs claim either North Carolina or Illinois law should govern this matter. (Doc. 372, p. 6). This assertion stands in stark contrast to the prior assertions of Plaintiffs concerning the correct state law *in this very case*. More than just a naked unsupported assertion concerning the correct application of Maryland law, Plaintiffs provided the following full-throated analysis under Illinois choice of law principles:

> Plaintiffs anticipate that Abbott will argue that North Carolina law applies to this case because Stacy Bartolini relocated to North Carolina during the third trimester of her pregnancy and Plaintiff H.B. was born in North Carolina. However, an analysis of the applicable choice-of-law rules indicates that these issues are governed by Maryland law. Because this action asserts state law claims, we look to the choice-of-law rules from Illinois, the state in which this Court sits, to determine which state's law governs Plaintiffs' claims. *See In re Bridgestone/Firestone Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1015 (7th Cir. 2002). Illinois choice-of-law rules presume that the law of the state where the plaintiff's injury occurred governs the plaintiff's suit unless there is another state with a "more significant relationship" to the action. *Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 903 (Ill. 2007). Here, the failure to warn occurred in Maryland and the majority of Plaintiff H.B.'s in utero exposure to Depakote occurred in Maryland, thus Maryland law applies.

(Doc. 87, p .3, n. 9); (Doc. 126, p. 7 n. 34). Plaintiffs provide no explanation as to why they now assert that either North Carolina or Illinois law applies to the case. Such a stark, unexplained inconsistency is troubling.

Illinois applies the most "significant relationship test" when resolving choice-of-law disputes. *Ingersoll v. Klein*, 262 N.E.2d 593, 596 (Ill. 1970) ("The local law which has the most significant relationship with the occurrence and with the parties determines

their rights and liabilities in tort."). For torts, Illinois has adopted the choice of law methodology that is embodied in the Second Restatement of Conflict Laws. *Townsend*, 879 N.E.2d at 903 (citing *Ingersoll*, 262 N.E.2d 593). "[T]he Second Restatement contemplates a two-step process in which the court (1) chooses a presumptively applicable law under the appropriate jurisdiction-selecting rule, and (2) tests this choice against the principles of § 6 in light of relevant contacts identified by general provisions like § 145 (torts) . . . ." *Id.*

In reference to the first step of the process, a presumption exists in Illinois choice-of-law analysis that the law of the state where the injury occurred should determine the rights and liabilities of the parties. *Id.* This presumption can be overcome if it can be shown that another state had a more significant relationship with the occurrence and the parties. *Id.* In this case, there is no dispute that H.B. developed spina bifida in Maryland. Rather, Plaintiffs' unexplained change in position asserts North Carolina is the "place of injury" because that is the location where—six months *after* conception—H.B.'s spina bifida was first discovered. Plaintiffs' reasoning rests upon a misapplication of Illinois' "discovery doctrine"—applicable in a statute of limitations analysis and not in a choice of law analysis.

The evidence in this case allows the Court to determine H.B. was injured within the state of Maryland. The extensive litigation that has taken place in this mass tort action has established as an undisputed fact that spina bifida occurs early in the pregnancy, specifically within the first twenty-eight days. (Doc. 372-3, p. 14) (Noting that the "[neural tube] [c]losure is complete by 28 days gestation. . . . When there is a

failure of the lower neural tube to close, a neural tube defect termed spina bifida or meningomyelocele occurs.") Ms. Bartolini conceived H.B. in Maryland in March 2004 and then continued to reside in Maryland until August 2004. (Doc. 348, p. 3); (Doc. 348-3, p.3); (Doc. 372-3, p. 4). The passage of several months between conception and Ms. Bartolini's move to North Carolina allows the Court to determine with certainty that the injury occurred in Maryland.

Given that no state has a more significant relationship to the tort, coupled with the strong presumption afforded to the "place of injury," Maryland law must be applied in this case. *See Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 903 (Ill. 2007).

II. Was the Warning Label Adequate?

Abbott asserts its spina bifida warnings were reasonable under Maryland law. (Doc. 348, p. 1). Abbott believes "[t]his case is distinguished from other Depakote cases in which, applying the law of other states, the Court has found that warning adequacy raises a fact issue." (Doc. 348, p. 2). Plaintiffs contend that Abbott has misinterpreted Maryland law and the question of whether Abbott provided an adequate warning "can only be resolved by the jury." (Doc. 372, p. 10).

Maryland law includes the learned intermediary doctrine. This doctrine "provides that manufacturers need only warn the prescribing physician and not the patient directly." *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 572 (D. Md. 2006); *see also Weinberger v. Bristol-Myers Co.*, 652 F. Supp. 187, 189-90 (D. Md. 1986) (stating the manufacturer's duty to warn in the area of prescription drugs is distinguished from drugs sold directly to consumers). The doctrine looks at the learned intermediary's

"entire field of knowledge, however gained. Even if a label's warnings are inadequate, the doctrine protects a manufacturer from liability provided the doctor has been sufficiently warned from other sources." *Ames*, 431 F. Supp. 2d at 572. When making determinations about the reasonableness of warnings, courts "must . . . bear in mind that the warnings are intended to be read by learned intermediaries who are presumed to have considerable medical training as well as the ability to access the medical literature if they require additional information." *Id.* at 573.

"A manufacturer has a duty to communicate an adequate warning of the dangers involved in the use of a product, as well as instructions for its safe use, if [the manufacturer] knows or has reason to know that product is likely to be dangerous." *Weinberger*, 652 F. Supp. at 190 (citing *Moran v. Faberge, Inc.*, 332 A.2d 11, 20 (Md. Ct. App. 1975)). "Under Maryland law, a warning is adequate if it 'explains the risk which allegedly caused the plaintiff's injury.' The warning must only be reasonable, not the best possible one." *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 572 (D. Md. 2006) (quoting *Lee v. Baxter Healthcare, Corp.* 1990 WL 27325, *5 (4th Cir. Feb. 27, 1990)).

Abbott asserts that the presence of the 1-2% spina bifida warning renders the label adequate as a matter of law, even though every judge faced with this argument has rejected this assertion. *See e.g., Z.H., et al., v. Abbott Labs., Inc.*, 14-CV-0176, 2016 U.S. Dist. LEXIS 135792, at *18-19 (N.D. Ohio Sept. 30, 2016); *B.F., et al., v. Abbott Labs., Inc.*, 12-CV-01760-CAS, 2016 U.S. Dist. LEXIS 42935, at *10 (E.D. Mo. Mar. 31, 2016); *In re Depakote*, 2015 WL 4776093 (Feb. 14, 2015 S.D. Ill.); *J.B., et al., v. Abbott Laboratories Inc.*, 13-CV-326-DRH-SCW, Doc. No. 180, at *5-11 (S.D. Ill. Apr. 14, 2014); *Barron v. Abbott*

Labs., No. SC96151, at *6-8 (Sept. 12, 2017). Still faithfully pushing this assertion, Abbott now seeks summary judgment under an apparent theory that Maryland law requires manufactures to merely "reference" a potential dangerous side effect:

> In fact, in a recent decision addressing the legal adequacy of the warnings accompanying Accutane, a prescription acne drug, about the risk of inflammatory bowel disease (IBD), a New Jersey intermediate appellate court identified Maryland as one of only a handful of U.S. jurisdictions in which "[i]t is enough . . . that IBD was *referenced* to render the warning adequate as a matter of law." *In re Accutane*, 2017 WL 3138003, at *34 (N.J. App., July 25, 2017) (emphasis added).FN2 Abbott went well beyond merely "referencing" spina bifida, making its warnings about that injury plainly sufficient under the controlling law of Maryland.

(Doc. 358, p. 2). Abbott's reliance on and emphasis of the word "referenced" in this case represents a myopic view of the cited decision and a tortured interpretation of Maryland law. Even if the Court were to exclude Plaintiffs' assertions concerning the failure to include the major malformation rates[2] and only focus on the spina bifida warning, there is sufficient evidence to create a material issue of fact that must be resolved by a jury.

There is no dispute that the 2004 label included the 1-2% risk of spina bifida. The inclusion of the specific incidence rate for spina bifida fails to make the label reasonable as a matter of law under the circumstances of this case, however, because significant flaws with the label remain reasonably disputed. For example, Plaintiff's regulation and drug labeling expert, Dr. Kessler, has previously testified that Abbott should have included instructions for doctors to use Depakote in women of childbearing potential only as a last resort. (Doc. 286, p. 121). There is a dramatic difference in the signal

[2] Dr. Kessler's testimony provides sufficient evidence that the Depakote label should have included the 10.7% major malformation rate in the 2004 label to survive summary judgment.

communicated by a label containing an instruction that expressly directs doctors to use a drug as a last resort compared to one without such an instruction. A reasonable jury could infer from Dr. Kessler's testimony that without the last resort warning the label did not provide proper instructions for safe use and thus was not reasonable.

Dr. Kessler also testified that, as of 1992, there was sufficient scientific evidence for Abbott to know that Depakote was much more dangerous than other antiepileptic drugs, specifically as it related to the risk of spina bifida. (Doc. 289, pp. 47-48, 57, 63). A jury could reasonably infer from the label and Dr. Kessler's testimony that while claiming "all antiepileptic drugs carry a risk of birth defects" was a true statement, it is materially misleading. A jury may, for example, draw the inference that by claiming "all antiepileptic drugs carry a risk of birth defects," Abbott negligently watered down the risk profile of Depakote by associating it with a class of drugs that carried a much lower risk of spina bifida. A jury may reasonably wonder why Abbott mentioned other competitor drugs at all in the label, especially when Depakote was known to carry *four times* the risk of the next competitor in its class. There is sufficient doubt as to the reasonableness of the 2004 Depakote warning label to preclude the Court from declaring it sufficient as a matter of law.

In viewing the evidence in the light most favorable to Plaintiffs, there is a genuine issue as to the adequacy of the label. Abbott's exclusion of the last resort instruction and the inclusion of the statement that "all antiepileptic drugs carry a risk of birth defects" prevent this Court from finding the label adequate as a matter of law. As to any remaining birth defects unrelated to spina bifida, the exclusion of the major

malformation rate is a material issue of fact that must be resolved by the jury.

Conclusion

For the reasons set forth above, the Court **DENIES** Abbott's Motion for summary judgment (Doc. 348).

IT IS SO ORDERED.

DATED: October 20, 2017

NANCY J. ROSENSTENGEL
United States District Judge